

# Exhibit 2

**From:** Keller, Penny (CMS/CCSQ) [REDACTED]  
**To:** Bennett, Sarah F. (CMS/CCSQ); Meyers, Penelope A. (CMS/CCSQ)  
**Sent:** 6/16/2015 1:49:55 PM  
**Subject:** RE: Theranos

Yes, Jan, Karen and I talked with the reporter on Friday. We didn't receive a complaint at CMS. However, the journalist did, and a complaint was submitted to NY State because it may have involved the NY PT program. Stephanie says the complaint was forwarded to CMS RO9 since Theranos is not license by NY, but Gary confirmed he did not get any complaint against Theranos. Complaint basically is that Theranos is running patient samples on its black box LDT, called "Einstein", but ran and reported PT results from the FDA cleared test system, not from the Eistein. Ahhhhhh....

PennyK.

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**From:** Bennett, Sarah F. [REDACTED]  
**Sent:** Tuesday, June 16, 2015 9:44 AM  
**To:** Keller, Penny (CMS/CCSQ); Meyers, Penelope A. (CMS/CCSQ)  
**Subject:** RE: Theranos

At this point they may just be collecting and either running at the CA or AZ lab or sending it to a reference lab.

What complaint has been received?

Did you and Karen talk to the reporter last week?

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**From:** Keller, Penny [REDACTED]  
**Sent:** Tuesday, June 16, 2015 9:40 AM  
**To:** Bennett, Sarah F. (CMS/CCSQ); Meyers, Penelope A. (CMS/CCSQ)  
**Subject:** FW: Theranos

FYI There's a few things going on with Theranos in the news; journalist, complaint, etc. This is the first time I've seen this test list. My first thought is which test platform are they running and reporting out patient samples, or are they running them on both and reporting out on both?

*Penny Keller*

Penny Keller  
Division of Laboratory Services  
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**From:** Keller, Penny (CMS/CCSQ)  
**Sent:** Monday, June 15, 2015 7:37 AM  
**To:** Dyer, Karen (CMS/CCSQ)  
**Subject:** FW: Theranos

Penny Keller

Division of Laboratory Services  
Survey & Certification Group, CMSC, CMS

[REDACTED]  
[REDACTED]  
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**From:** Heather King [hking [REDACTED]]  
**Sent:** Friday, June 12, 2015 11:21 PM  
**To:** Keller, Penny (CMS/CCSQ)  
**Subject:** RE: Theranos

Peggy – Please find attached a clinical lab test list, which indicates our LDTs. My understanding is that you were shown an earlier version of this in the past, when you met with Theranos in person in DC. The list is subject to change so please don't hesitate to ask for updates from time to time, and let me know if there is anything else you need.

Sincerely,

Heather

**From:** Keller, Penny (CMS/CCSQ) [REDACTED]  
**Sent:** Thursday, June 11, 2015 11:00 AM  
**To:** Heather King  
**Subject:** RE: Theranos

Very much appreciated. Hope the weather is nicer out there than it is here.

*Penny Keller*

Penny Keller  
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**From:** Heather King [REDACTED]  
**Sent:** Thursday, June 11, 2015 1:55 PM  
**To:** Keller, Penny (CMS/CCSQ)  
**Subject:** RE: Theranos

Yes! I'm having someone compile that list for you. (I just moved out here, officially, this past weekend so discussed that with the folks here when I started in the office on Monday, and they're working to get that list to me this week.)

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**From:** Keller, Penny (CMS/CCSQ) [REDACTED]  
**Sent:** Thursday, June 11, 2015 10:53 AM  
**To:** Heather King  
**Subject:** RE: Theranos

Hello Heather,

I wanted to follow up and see if you could share the names of the LDT tests that Theranos was currently performing.

Kind regards,

*Penny Keller*

Penny Keller

Division of Laboratory Services  
CMS/SCG/CCSQ

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

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**From:** Heather King [REDACTED]  
**Sent:** Wednesday, May 27, 2015 5:30 PM  
**To:** Keller, Penny (CMS/CCSQ)  
**Subject:** Theranos

Dear Penny,

As you may know, we have come under attack from other laboratories, especially since we have publicly begun working to support FDA regulation of LDTs. See our public comment attached here. These persons are spreading false and damaging rumors about Theranos and trying to engage former Theranos employees in making defamatory statements, including false statements about Theranos' interactions with CLIA regulators. See our recent letter to the Sonora Quest & Quest Diagnostics General Counsel here. We take this matter very seriously and are endeavoring to correct any misrepresentations they make. I write to give you a heads up that we are directing the journalists they are trying to spread mis-information with to reach out to CLIA and FDA directly.

I would also ask for your assistance in setting the record straight.

As we always have, our goal at Theranos is to be fully transparent and welcoming to regulators and inspectors. To the extent anyone has contacted you concerning the recent misstatements, or if you have questions about any of our processes, we welcome your inquiries and would of course welcome you back to our facilities to conduct any additional inspections you would like at any time. Please let us know.



It would be helpful to us if you would confirm your understanding of some basic facts. We do not believe that any of them is controversial, but a written confirmation from you would go a long way toward helping us rebut false allegations. A simple return email would suffice. Of course, if you have any questions or revisions, I welcome them as well.

1. CLIA regulators understand that Theranos conducts standard proficiency testing processes for all analytes for which proficiency testing is available. For applicable analytes, Theranos institutes alternative assessment protocols (AAP) as required by the relevant statutes. Theranos Proficiency Testing and AAP reports shared during inspection show that all tests offered by Theranos meet CLIA performance criteria. Theranos' proficiency testing and alternative assessment protocols have been disclosed to CLIA regulators in full, and comply with all applicable rules and regulations.
2. CLIA regulators understand that tests offered by Theranos' lab have met or exceeded all performance requirements under CLIA for all analytes tested.
3. CLIA regulators are aware that Theranos operates a high-complexity CLIA facility that performs FDA cleared and approved tests and LDTs. Theranos has made its full laboratory and all tests available for inspection on multiple occasions.
4. Theranos' full laboratory has in fact been inspected by CLIA inspectors.

Sincerely,

Heather King  
General Counsel  
Theranos, Inc.